MAY 12 2000 K001267

Special 510(k) Premarket Notification
GE Medical Systems - System FiVe with Immersible IO Probes
April 17, 2000

Attachment B:

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

Section a):

1. Submitter: GE Medical Systems
PO Box 414
Milwaukee, WI 53201

Contact Person: Allen Schuh,
Manager, Safety and Regulatory Engineering
Telephone: 414-647-4385; Fax: 414-647-4090

Date Prepared: April 14, 2000

2. Device Name: GE Vingmed System FiVe Diagnostic Ultrasound with immersible IO probes.
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO

3. Marketed Device: GE Vingmed System FiVe diagnostic ultrasound system, 510(k) Numbers K963315 and K991842 currently in commercial distribution.

4. Device Description: The GE Vingmed System FiVe with immersible IO probes is a full featured echocardiography imaging and analysis system. It consists of a mobile console approximately 67 cm wide, 110 cm deep and 140 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, small flat-panel displays and a color video CRT display monitor. This modification will provide users with alternate methods in preparing for intraoperative applications.

5. Indications for Use: The GE Vingmed System FiVe with immersible IO probes is intended for use by a qualified physician for ultrasound evaluation of abdominal, cardiac, pediatric, fetal, intraoperative (non-neurological), transesophageal, transvaginal, transrectal, peripheral vascular, small organ, neonatal and adult cephalic.

6. Comparison with Predicate Device: The GE Vingmed System FiVe with immersible IO probes is of a comparable type and substantially equivalent to the currently marketed GE Vingmed System FiVe. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same basic design, construction, and materials, and has the same intended uses, operating modes and probes as the predicate device.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, sterilization effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and EN 46001 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vingmed System FiVe with immersible IO probes is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2000

Allen Schuh
Manager, Safety & Regulatory Engineering
GE Medical Systems
P.O. Box 414
Milwaukee, Wisconsin 53201

Re: K001267
Modification (change of reprocessing) to GE Vingmed System FiVe
Dated: April 19, 2000
Received: April 20, 2000
Regulatory Class: II
21 CFR 892.1550/Procode: 90 IYN
21 CFR 892.1560/Procode: 90 IYO
21 CFR 892.1570/Procode: 90 ITX

Dear Mr. Schuh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vingmed System FiVe Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

i8Lv
i13Lv

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note*: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul Gammell at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001267

Special 510(k) Premarket Notification
GE Medical Systems - System FiVe with Immersible IO Probes
April 17, 2000

Diagnostic Ultrasound Indications for Use Form

GE Vingmend System FiVe System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)		P	P	P		P	P		P	
Neonatal Cephalic		P	P	P	P	P	P		P	
Adult Cephalic		P	P	P	P	P	P		P	
Cardiac		P	P	P	P	P	P		P	P
Transesophageal		P	P	P	P	P	P		P	
Transrectal		P	P	P		P	P		P	
Transvaginal		P	P	P		P	P		P	
Transuretheral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis. Small organ includes breast. Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M, Combined includes B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001267

Prescription User (Per 21 CFR 801.109)

K001267

Special 510(k) Premarket Notification
GE Medical Systems - System FiVe with Immersible IO Probes
April 17, 2000

Diagnostic Ultrasound Indications for Use Form

GE Vingmend System FiVe with i8Lv Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	P
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis.

Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M,

Combined includes B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,

Other mode is Strain Rate Imaging, K991842

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K001267

Prescription User (Per 21 CFR 801.109)

K001267

Special 510(k) Premarket Notification
GE Medical Systems - System FiVe with Immersible IO Probes
April 17, 2000

Diagnostic Ultrasound Indications for Use Form

GE Vingmend System FiVe with i13Lv Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P	P	P	P		P	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	P
Transesophageal										
Transrectal										
Transvaginal										
Transuretheral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric and cardiac analysis.

Intraoperative includes abdominal, thoracic and PV, Color Doppler includes Color M,

Combined includes B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD,

Other mode is Strain Rate Imaging, K991842

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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